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June 30, 2003

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Application No. 09/667,188
Filed: September 21, 2000
Title: Nucleic Acid Molecules and Other Molecules Associated with Plants
Applicants: ANDERSEN *et al.*
Atty. Docket: 16517.001/38-21(51464)B

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office (PTO):

1. an Appellant's Brief (in triplicate); and
2. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to our courier.

Applicants request that the following fee be charged to Deposit Account No. 50-2387 referencing docket number 16517.001/51464B:

$ 320.00 appeal brief fee

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any fees, other than the above fee ($320), are due in conjunction with this filing. However, if any additional fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit Account No.

50-2387 referencing matter number 16517.001/51464B. A duplicate copy of this letter is enclosed.

Respectfully submitted,

David R. Marsh (Reg. Attorney No. 41,408)
Dawn Gardner Krosnick (Reg. Attorney No. 44,118)

Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:			
ANDERSEN *et al.*		Art Unit:	1634
Appln. No.:	09/667,188	Examiner:	D. Gunter
Filed:	September 21, 2000	Atty. Docket:	16517.001/38-21 (51464)B
For:	***Nucleic Acid Molecules and Other Molecules Associated With Plants***		

APPELLANT'S BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-identified patent application. A Notice of Appeal was filed on April 28, 2003. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Appellant is unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1, 2 and 11-15 are pending. Claims 1, 11 and 13 are independent. Claims 1, 2 and 11-15 stand finally rejected under 35 U.S.C. §§ 101 and 112, first paragraph. Appellant appeals all of the rejections of claims 1, 2 and 11-15.

4. Status of Amendments

Applicants have not filed any amendments subsequent to the Final Office Action mailed January 29, 2003 (Paper No. 11) ("Final Office Action"), in this case.

5. Summary of Invention

The invention is directed to a nucleic acid molecule that encodes a plant protein or fragment thereof comprising the nucleic acid sequence of SEQ ID NO: 1. Specification at page 9, line 24 through page 10, line 3. The present invention is also directed to a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 and a complement thereof. *Id.* The present invention is also directed to a nucleic acid molecule having between 95% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 1 or complement thereof. Specification at page 19, line 17 through page 20, line 9.

6. Issues

The issues in this Appeal are:

(a) whether claims 1, 2 and 11-15 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(b) whether claims 1, 2 and 11-15 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because the claimed invention purportedly lacks utility; and

(c) whether claims 13-15 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged insufficiency of written description.

7. Grouping of Claims

The patentability of claims 1, 2 and 11-15 is addressed together in Sec. 8.A through 8.C below. The separate patentability of claims 13-15 is addressed in Sec. 8.D below. A copy of the claims on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility . . . where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, the ability to identify the presence or absence of a polymorphism in a population of wheat plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecules provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. In addition, because the specification teaches how to make and use the claimed nucleic acid molecules for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate written description of the claimed nucleic acid molecules that demonstrates Applicants' possession of the claimed invention. The genus of claimed nucleic acid molecules, *i.e.*, the genus of nucleic acid molecules comprising the nucleic acid sequence of SEQ ID NO: 1, has been described by the recitation of a structural feature, *e.g.*, the nucleotide sequence of SEQ ID NO: 1, which distinguishes molecules in the claimed genus from molecules not in the claimed genus. Because the specification demonstrates that Applicants had possession of, and have provided an adequate description of, the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112, first paragraph.

B. The Claimed Nucleic Acids Have Legal Utility

Pending claims 1, 2 and 11-15 were erroneously rejected under 35 U.S.C. § 101 for allegedly not being supported by a specific, substantial, and credible utility or by a well

established utility. Final Office Action at pages 2-3. Although the Examiner has acknowledged that the specification identifies that the claimed nucleic acid molecules can be used for identifying promoters involved in gene regulation, determining whether a plant contains a mutation, and acting as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (Final Office Action at page 2), the Examiner contends that these are non-specific uses because they "are applicable to polynucleotides in general and not particular or specific to the polynucleotide claimed." Final Office Action at page 3. Furthermore, the Examiner contends that these and the utilities disclosed in the specification for the claimed nucleic acid molecules are "neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds." Final Office Action at page 2.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention

must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits. For example, they can be used for identifying promoters involved in gene regulation, for determining whether a plant contains a mutation, and for use acting as molecular tags to isolate genetic regions, isolate genes, map genes, and determine gene function. *See*, for example, the specification at page 38, line 4, to page 39, line 12; and page 51, line 15, to page 56, line 25. Any of these utilities described alone is enough to satisfy 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and because they have done so in the present case, the premise of the rejection under 35 U.S.C. § 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide a Specific Benefit, *i.e.*, They Have a Specific Utility

The Examiner acknowledges that the instant specification describes multiple utilities for the present invention, including identifying promoters, detecting mutations, and genetic mapping. Final Office Action at page 2. The specification also discloses additional utilities for the claimed nucleic acid molecules,[1] including introduction of the claimed nucleic acid molecules into a plant or plant cell (either as sense or antisense inhibitors), which can then be used to screen for compounds such as an herbicide. Specification at page 79, line 3 through page 81, line 15. For example, a compound can be provided to both an antisense plant and a control plant (no antisense) and the effect of the compound on the plant can be monitored. Such a screen is analogous to a cell-based assay, which has a legally sufficient utility.[2] Other utilities disclosed in the specification include use of the claimed nucleic acid molecules to measure the level of

[1] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

[2] *See, e.g.*, MPEP § 2107 at page 2100-32.

mRNA in a sample,[3] and use as molecular markers.[4] *See, e.g.*, the specification at page 51, line 15, to page 52, line 11.

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is the use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. *See, e.g.,* specification at page 38, line 19, to page 47, line 2. The Examiner argues that this utility, like all of the asserted utilities, is not specific or substantial, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms is not a legal utility. *See* Final Office Action at pages 2-3.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates such utilities by asserting that these utilities "are not specific because they are applicable to nucleic acids in general and not only to the claimed invention in particular." Final Office Action at page 6. However, the fact that a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening

[3] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, drought stress. Contrary to the Examiner's assertions, this use is not using the claimed nucleic acid molecules to identify a " 'real world' use." *See* Final Office Action at page 9. It is a **use** of the claimed nucleic acid molecules in a real world context.

[4] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of a polymorphism is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[5] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Additional uses for the claimed nucleic acid molecules are as a probe for other molecules, and as a source of primers. The Examiner suggests that these uses are not legal utilities because "[a]ny nucleic acid molecule from any source can be used to determine the presence of polymorphisms, isolate specific promoter sequences, and obtain nucleic acid homologues, and therefore the asserted utilities are non-specific." Final Office Action at page 6. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used, via

[5] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

hybridization, in real world applications such as to isolate nucleic acid molecules of other plants and organisms, such as maize, cotton, soybean and wheat.[6] Specification at page 29, line 25 through page 26, line 14. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using the claimed nucleic acid molecules is the promoter of the gene corresponding to that claimed nucleic acid molecule. Further, Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 37, lines 5-24. The Examiner denigrates that utility when he asserts that the disclosed utilities are "applicable to nucleic acids in general and not only to the claimed invention in particular." Final Office Action at page 6.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *i.e.,* chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

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[6] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acid molecules. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter active in wheat plants. *See, e.g.,* specification at page 33, line 25 through page 35, line 16. Random nucleic acid molecules are not similarly suitable. Furthermore, even if a random nucleic acid molecule provided a better starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

The Final Office Action also appears to assert that the disclosed uses are legally insufficient because they are not "substantial" utilities. Final Office Action at page 3. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). " 'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[7]

[7] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (CCPA 1974).

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, *e.g.*, to detect the presence or absence of polymorphisms. One example of the detection of polymorphisms providing an immediate benefit to the public is that it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Cf. Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases

in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[8] A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107.02 at 2100-40.

Applicants have explicitly identified specific and substantial utilities, not only in the specification, but in Applicants' Response dated November 13, 2002. "To violate [35 U.S.C. §] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1, 2 and 11-15 under 35 U.S.C. §101 is improper and should be reversed.

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[8] Examples of incredible utilities are given in MPEP § 2107 at page 2100-34, and include: an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

C. The Claimed Nucleic Acid Molecules Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 1, 2 and 11-15 were erroneously rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Office Action at pages 3 and 4. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection is improper and should be reversed. *See, e.g., In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q. 2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (B.P.A.I. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides an Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that SEQ ID NO: 1 meets the written description provision of 35 U.S.C. § 112, first paragraph (Final Office Action at page 11), the adequacy of the written description of claims 13-15 has been challenged by the Examiner because the claimed subject matter was allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) . . . had possession of the claimed invention." Final Office Action at page 10. The bases for the Examiner's challenge are apparently that (1) one of skill in the art would allegedly conclude that Applicants were not in possession of the claimed nucleic acid molecules, and (2) there is allegedly an insufficient written description to support the genus encompassed by the claim. Final Office Action at pages 10-11. These are not proper bases for a written description rejection of a "comprising" claim. If

they were, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if every nuance of the invention was not expressly described, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. After reading the present specification, a person of ordinary skill in the art would understand that Applicants had possession of nucleic acid molecules comprising SEQ ID NO: 1 as well as nucleic acid molecules having between 95% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 1 or complement thereof, and therefore, the claimed invention.

Applicants have provided the nucleic acid sequences required by the claims, *i.e.*, SEQ ID NO: 1, as well as, for example, vectors comprising the nucleic acid sequence (*see, e.g.*, specification at page 62, line 14 through page 70, line 25); hybridization conditions which may be used with the nucleic acid molecules of the present invention (*see, e.g.*, specification at page 18, line 3 through page 19, line 16); single nucleotide polymorphisms including the claimed nucleic acid molecules (*see, e.g.*, specification at page 26, line 3 through page 27, line 13); and binary artificial chromosomes (BIBACs) and other systems that may be used to introduce the claimed nucleic acid molecules into a host cell (*see, e.g.*, specification at page 70, lines 20-25).

The fact that the claims at issue are intended to cover molecules that include the recited sequence joined with additional sequences, or that have a recited percent identity to the recited sequence, does not mean that Applicants were any less in possession of the claimed nucleic acid molecules.[9] It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

Applicants have provided in the present disclosure not only the nucleotide sequence required by the claims (*i.e.*, SEQ ID NO: 1), but also several variations including and directed to the claimed nucleic acid molecules. For example, the present specification describes vectors comprising the claimed nucleic acid molecules (*see, e.g.,* specification at page 62, line 14 through page 70, line 25), and describes how to make the nucleic acid molecules and the libraries from which they were originally purified. *See, e.g.,* specification at page 86, line 21 through page 89, line 11 (Examples 1-2)). Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequence (*i.e.,* SEQ ID NO: 1) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[10] for example, at page 29, line 25 through page 30, line 14 (describing fusion peptide molecules encoded by the claimed nucleic acid molecules); page 17, lines 22-26 (describing sequences with labels to facilitate detection); page 57, line 6 through page 58, line 24 (describing site directed mutagenesis); page 82, line 16 through page 83, line 4 (citing references describing the construction, manipulation and isolation

[9] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then she goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

[10] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

of nucleic acid macromolecules); and page 53, line 7 through page 54, line 2 (describing *in situ* hybridization using the claimed nucleic acid molecules).

Moreover, the court determined, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002), that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d at 1615. Furthermore, it is well established that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981)).

(2) Applicants Have Described the Claimed Invention

The Final Office Action asserts that, because the specification "provides no teaching or guidance which correlates the sequence of SEQ ID NO: 1 to its function, which amino acids in the protein encoded by SEQ ID NO: 1 are critical to its function, or how to modify SEQ ID NO: 1 to obtain any specific homolog, mutant, or variant . . ", Applicants have allegedly not adequately disclosed the claimed genus. Final Office Action at page 11. The Examiner appears to assert that each nucleic acid molecule within the claimed genus must be described by its complete structure. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed common structural features, for example, the nucleotide sequence of SEQ ID NO:1. The respective common structural feature (the nucleotide

sequence of SEQ ID NO: 1) is shared by every nucleic acid molecule in this claimed genus, and it distinguishes the members of this claimed genus from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1. If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. Furthermore, one skilled in the art would readily recognize if a nucleic acid molecule contains a nucleic acid sequence having, for example, 95% sequence identity with a nucleic acid molecule of SEQ ID NO: 1.[11] The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1, or has a stated sequence identity to SEQ ID NO: 1, or it does not. Furthermore, one skilled in the art would readily recognize a claimed nucleic acid molecule comprising a region having a single nucleotide polymorphism upon reading the disclosure of the present specification.

One skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, claims 13-15 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

[11] The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA contains a nucleic acid sequence having 96% sequence identity with a nucleic acid molecule of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid molecule having 96% sequence identity with a nucleic acid molecule of SEQ ID NO: 1, and so forth.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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Date: June 30, 2003

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APPENDIX A

1. A substantially purified nucleic acid molecule that encodes a plant protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1.

2. The substantially purified nucleic acid molecule of claim 1, wherein the plant protein or fragment thereof is a wheat protein or fragment thereof.

11. A substantially purified nucleic acid molecule comprising a nucleic acid sequence selected from the group of SEQ ID NO: 1 and a complement thereof.

12. The substantially purified nucleic acid molecule according to claim 11, wherein said nucleic acid molecule consists of a nucleic acid sequence selected from the group of SEQ ID NO: 1 and a complement thereof.

13. A substantially purified nucleic acid molecule having between 95% and 100% sequence identity with a nucleic acid molecule of SEQ ID NO: 1 or complement thereof.

14. The substantially purified nucleic acid molecule of claim 13, wherein said substantially purified nucleic acid molecule has between 99% and 100% sequence identity with SEQ ID NO: 1 or complement thereof.

15. The substantially purified nucleic acid molecule according to claim 13, wherein said nucleic acid molecule comprises a region having a single nucleotide polymorphism.